Honorary Research Associates

ISLHD recognises the potential benefits in undertaking research in collaboration with persons who are not employees but who bring special expertise, skills and knowledge. While the ISLHD does not pay any salary or wages associated with these appointments, it still has responsibilities related to its duty of care and thus must undertake certain due diligence procedures.

Persons may apply for appointment as an Honorary Research Associate. Please contact the Research Support Office for further information.

Collaborative Research

There may be additional documentation necessary for collaborative research. Consult the ISLHD Research Support Office for further advice.

Links

National Statement of Ethical Conduct in Human Research:
http://www.nhmrc.gov.au/guidelines/publications/e72

Australian Code for the Responsible Conduct of Research:
http://www.nhmrc.gov.au/guidelines/publications/r39

NSW Ministry of Health Research Ethics and Governance:
http://www0.health.nsw.gov.au/ethics/research/governance.asp

Therapeutic Goods Administration:
http://www.tga.gov.au/

Medicines Australia:
http://medicinesaustralia.com.au/issues-information/clinical-trials/

Clinical Research is integral to driving quality, efficiencies and knowledge based practice and so enables improved health care and better treatments, therapies and services.

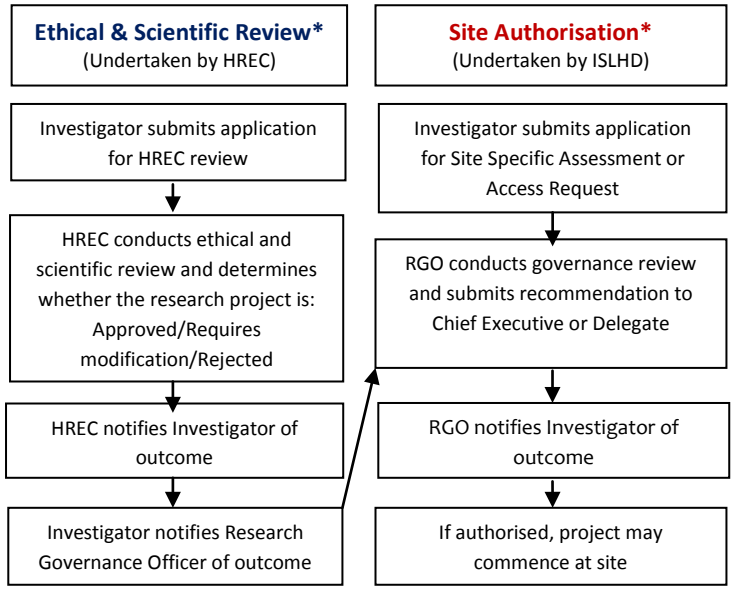
24 May 2013

Overview of Processes for obtaining Human Research Ethics Committee (HREC) approval and Site Authorisation of research taking place in ISLHD

Pre-submission

Before submitting a research proposal for ethical and governance review it is important to:

- Familiarise yourself with the key policies and guidelines that need to be taken into account in the design and conduct of the proposal;
- Carefully plan your project to ensure that the research protocol clearly describes the design and performance of each aspect of the proposal and details the ethical considerations involved;
- Determine the level of risk to participants and, if unsure, discuss the project with HREC Executive Officer and RGO;
- Determine whether the project has specific review requirements in addition to review by a local or lead HREC (e.g. research involving persons in custody, research affecting the health and well-being of Aboriginal people and communities, research requiring access to state-wide data collections, clinical trials with persons unable to provide consent);
- If a collaborative research project that all parties have been involved in the development of the proposal, have a clear documented understanding of and have agreed to their expected involvement, and
- Obtain the support for the project from ISLHD Head of Department including confirming ISLHD resources are available from the Head of Department.



* It is recommended that both the Ethics Application and the Site Specific Assessment application are submitted simultaneously.

NSW GOVERNMENT Health
Illawarra Shoalhaven Local Health District

Information for Researchers

Interested in doing a research project but not sure where to start?

The first thing is discuss the idea with your immediate manager to work out whether it can be supported within your team. Once you have done that you can start creating the study design. We can help you with the research process by assisting with the study design and highlighting the practicalities of undertaking research in the clinical setting.

For further advice/support contact the Research Support Office on:

Phone: 4253 4800
Email: ISLHDresearch@sesiahs.health.nsw.gov.au

Wollongong Hospital
Block C, Level 8
Locked Mail Bag 8808
South Coast Mail Centre NSW 2521

Overview

ISLHD has a primary responsibility to protect the rights and interests of research participants and to that end must ensure that human research is conducted following appropriate ethical and scientific review, accords with agreed ethical and legislative standards, does not compromise the rights and interest of participants and the process for participant consent is robust and transparent. Whether involving patients or healthy volunteers, research will only be conducted by individuals with the appropriate scientific training and qualifications and under the supervision of a competent and appropriately qualified ISLHD clinician.

Before authorising human research to be conducted at sites or involving participants (including tissue or data) for whom it is responsible, ISLHD must be satisfied that the proposed research meets the necessary ethical, legal and regulatory standards as well as institutional requirements. Two complimentary processes are used to inform this decision – ethical and scientific review by a Human Research Ethics Committee (HREC) and a site assessment or governance review which takes into account institutional-specific issues such as resources, available expertise, budget, risk management and contractual arrangements.

If the research is to be conducted at more than one site (Local Health District) in the NSW Public Health System only a single ethical and scientific review is required if this is conducted by an accredited Lead committee. However, a specific governance review will be required for each site.

The procedures implemented in ISLHD to authorise human research accord with the policies of the NSW Ministry of Health for NSW Public Health Organisations and the NHMRC Research Governance Handbook (2011).

Ethical & Scientific Review

Local Human Research Ethics Committee (HREC)

The local HREC is a Lead joint committee of the University of Wollongong and the Illawarra Shoalhaven Local Health District.

The office that manages this committee is based at the University of Wollongong, contact details are below:

Research Services Office –
Phone: 02 4221 3386
Email: rso-ethics@uow.edu.au

Website:
http://www.uow.edu.au/research/ethics/human/index.html

Types of ethical and scientific review

HRECs established by NSW Public Health Organisations provide full and expedited ethical and scientific review. Full HREC review must be undertaken for all research that involves more than low risk to participants, as defined in the *National Statement.* Expedited HREC review can be conducted for research that only involves low or negligible risk to participants, as defined in the *National Statement*.

Research with specific review requirements

Certain research projects must satisfy specific review requirements in addition to review by a local or lead HREC, before they take place in NSW Public Health Organisations. This includes research involving persons in custody or staff of NSW Justice Health, research affecting the health and wellbeing of Aboriginal people and communities, research requiring access to state-wide data collections and clinical trials with persons unable to provide consent.

Which application form should I complete?

Applications for ethical and scientific review must be submitted using either the:
(i) National Ethics Application Form (NEAF) for applications for full HREC review; or
(ii) Application Form for Ethical and Scientific Review of Low and Negligible Risk Research for applications for expedited HREC review.

The forms must be completed online via the Online Forms Website at https://ethicsform.org/au/

Research Governance - Site Authorisation

Research Governance is the framework by which institutions, investigators and their managers share responsibility and accountability for research conducted according to ethical principles, scientific, regulatory and professional standards and principles of risk management. Site authorisation is one aspect of research governance.

Types of site authorisation

1. Site Specific Assessment

A Site Specific Assessment (SSA) must be completed for all research projects to be conducted at sites under the control of NSW Public Health Organisations, even projects involving low or negligible risk to participants.

2. Access Request Form

An access request review must be completed for research that requires support from a Public Health Organisation in the form of access to participants, tissue or data but does not involve the conduct of research at that Public Health Organisation.

Which application form should I complete?

Applications for SSA must be submitted using either the:
(i) SSA Form for research projects that have been submitted for full HREC review; or
(ii) SSA Form for Low and Negligible Risk Research for research projects that have been submitted for expedited HREC review; or
(iii) Access Request Form. Only one access request per RGO is required, even if the project requires access from a number of facilities, locations or services covered by that RGO.

The forms must be completed online via the Online Forms Website at https://ethicsform.org/au/

Once the forms are completed online, they will need to be printed out and signed by all investigators listed and the ISLHD Heads of all Departments involved in the project. The completed SSA or ARF together with copies of all documents submitted to the HREC are submitted to the RGO for governance review.